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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,425	07/03/2001	Roberto Valducci	242/9-1568	1890

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1615	14

DATE MAILED: 03/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/898,425	Applicant(s) ROBERTO VALDUCCI	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears n the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Examiner acknowledges receipt of amendment D filed 01/23/03. New claims 23-34 are pending.

Claim Rejections - 35 USC § 112

1. Claims 23-34 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because "the active ingredient being separated into a plurality of portions" is vague. For examination purposes the active ingredient is interpreted as being in the form of granules.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim Rejections - 35 USC § 102

2. Claims 23, 24, 28 and 30-34 remain rejected under 35 U.S.C. 102(e) as being anticipated by Yajima et al. (US 5,972,373).

Applicant argues that Yajima does not anticipate the claims because Yajima's compositions does not provide multiphasic release of active ingredient "utilizing a plurality of active ingredient portions combined with a corresponding plurality of pH dependent soluble polymers or mixtures of polymers."

3. Applicant's arguments filed 1/23/03 have been fully considered but they are not persuasive.

Applicant claims a pharmaceutical formulation comprising an active ingredient where the active ingredient is separated into plurality of portions and each plurality of portions is combined with polymers whose solubility is pH dependent; the pH dependent polymers are recited in claims 31-33. Plurality of portions is interpreted as granules or powders. The recitation of "formulation for multiphasic release" is future intended use. The prior art only has to teach the composition. Yajima teaches granules and the polymers of the instant claims.

Yajima teaches a composition comprising macrolide antibiotics (column 2, lines 38-48) and polymers (column 2, lines 55-57). The composition is formulated into granules, powders, capsules, tablets and dry syrups (column 3, lines 15-18) and these formulations are enteric coated (column 3, line 48). The composition further comprises excipients (mannitol, carboxymethylcellulose), disintegrants (starch and crystalline cellulolse), binders (hydroxypropylmethyl cellulose and propyleneglycol alginate), lubricants (stearic acid) and antioxidant (BHT, BHA and alpha-tocopherol and citric acid). See column 3, lines 1-48). The coating agent includes hydroxypropylmethyl cellulose phthalate, hydroxypropylmethyl cellulose acetate succinate and the composition further comprises dyestuff and titanium oxide (column 3, lines 58 and 59). Claims are broadly directed to active agents and polymer and a composition meeting the limitations of claim 1 would have the release profile recited in claim 3.

4. Claims 23, 27, 29, 30-34 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kjorn es et al. (US 4,713,248).

Applicant argues that the instant invention is a system that releases portions of the active ingredient during transport through the intestine.

5. Applicant's arguments filed 1/23/03 have been fully considered but they are not persuasive.

6. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., the release of active ingredient during transport through the intestinal tract) is not recited in the rejected claim(s).

Kjorn es teaches a controlled release multiple unit formulation comprising active agents coated with inner and optional outer film layers (column 2, lines 38-60). The formulation is in the form of capsules, sachets or tablets (column 6, lines 20-40). The inner film layer is a film-forming agent selected from carboxymethylcellulose and hydroxypropylmethyl cellulose, to name a few of the polymers listed in column 3, lines 46-59. The outer film layer is a film-forming agent and examples are hydroxypropylmethylcellulosephthalate, celluloseacetatephthalate, polyvinylacetatephthalate or mixtures thereof (column 5, lines 13-33). Kjorn es further teaches that the formulation may comprise of mixtures of diffusion coated and uncoated units where the active agents are the same or different (column 6, lines 30-41); EUDRAGIT is an example of diffusion coating materials in Kjorn es (column 8, lines 39-44). Active substances including substances having pH independent and pH dependent solubilities are listed in column 7, line 20 to column 8 line 27. Kjorn es anticipates the claims.

7. Claims 23, 26, 28, 31 and 32 rejected under 35 U.S.C. 102(b) as being anticipated by Shah et al. (US 5,482,718).

Applicant presented no argument as to why the Shay reference would not anticipate the claims.

Shah teaches a multiplayer tablet comprising a core, erodible polymer layer and an enteric coating layer (abstract). The core comprises 5-aminosalicylic acids, which is mesalazine (see Sandborn et al, US 5,889,028, column 8, lines 19-24 for teaching of mesalazine as 5-ASA), microcrystalline cellulose, polyvinylpyrrolidone, magnesium stearate, mannitol and croscarmellose (example II). The erodible polymer layer comprises hydroxypropylmethylcellulose, microcrystalline cellulose, polyvinylpyrrolidone and magnesium cellulose; and the enteric coating layer comprises hydroxypropyl methylcellulose phthalate (example II). Shah anticipates the claims.

Claim Rejections - 35 USC § 103

8. Claim 33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US 5,482,718).

Applicant argues that in the invention the active ingredients are separated into portions for multiphasic release in accordance with the solubility of corresponding polymer.

9. Applicant's arguments filed 1/23/03 have been fully considered but they are not persuasive.

It is noted that the feature upon which applicant relies (i.e., the release of active ingredient during transport through the intestinal tract) is not recited in the rejected claim(s).

Shah clearly teaches the formulation of the application except that Shah is silent on the different types of hydroxypropyl methylcellulose phthalate. But since Shah is silent on the types of hydroxypropyl methylcellulose phthalate, Shah teaches all the types of hydroxypropyl

methylcellulose phthalate. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the multi-layer tablet formulation of Shah using all the type of hydroxypropyl methylcellulose phthalate because Shah teaches all types. Regarding claim 20, Shah teaches 40 mg of 5-aminosalicylic acids and the 100-3000 mg of 5-aminosalicylic acids in the claim represents optimization of the amount of the active ingredient that would be delivered to the colon upon dissolution of the tablet.

OTHER MATTERS: It appears that the inventive formulation comprises coated granules A, coated granules B and coated granules C where each set of granules contains active agent and where the coating for granule A is different from the coating for granule B and C. The generic claim as written does not convey the invention.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
March 26, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600